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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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ROBERT S. SILVER

HM22/1024

EXAMINER

PESELEV, E

CAESAR, RIVISE, BERSTEIN, COHEN & POKOTI
12TH FLOOR, SEVEN PENN CENTER

ART UNIT

PAPER NUMBER

1635 MARKET STREET
PHILADELPHIA PA 19103-2212

1623

DATE MAILED:

10/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

29/227,749

Applicant(s)

Examiner

Group Art Unit

1623

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 8/1/01
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 8-38 is/are pending in the application.
- Of the above claim(s) 18-30 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 8-17 and 31-38 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

In view of the Supplemental Amendment and Declaration submitted August 9, 2001, the Final Rejection of August 31, 2001 is herein withdrawn.

Claims 18-30 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. Election was made **without** traverse in Paper No. 5.

Applicant's election without traverse of Group I, claims 1-17, species macrolide in Paper No. 5 is acknowledged.

Claims 31-38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of Alzheimer's disease in a living being having Chlamydia pneumoniae infection, does not reasonably provide enablement for the treatment of Alzheimer's disease in a living being not infected with Chlamydia pneumoniae. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Applicant has not provided any evidence that the claimed methods are useful in treating Alzheimer's patients not infected with Chlamydia pneumoniae.

Claims 8-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shor et al (U.S. Patent No. 5,424,187) in combination with Koskiniemi et al (Eur Neurol 1996; 36:160-163).

Shor et al disclose the use of a macrolide alone or in combination with an antiinflammatory agent for the treatment of Chlamydia pneumoniae infection (column 2, lines 67-68 and column 3, lines 1-10) but do not disclose the treatment of said infection in central nervous system (CNS). However, since Koskiniemi et al disclose Chlamydia pneumoniae infections associated with CNS, a person having ordinary skill in the art at the time the instant

invention was made would have been motivated to treat any disease which involves infection by C. pneumoniae of CNS with a macrolide or a macrolide in combination with an antiinflammatory agent because the results obtained from such treatment would have been expected.

Applicant's arguments filed August 9, 2001 have been fully considered but they are not persuasive insofar as the above rejection relates to the claims.

The Declaration submitted has been considered but has not been found persuasive. The declaration provides a number of accounts of individuals who have experienced some level of improvement of their Alzheimer's disease following treatment of antibiotics. Said accounts have not been found persuasive since it is not clear from the accounts what antibiotics were taken at what dosages and whether individuals had C. Pneumoniae infection. Also, any progress has not been measured and cannot be evaluated.

Exhibit C has also been considered but it is not clear if any improvement shown is statistically significant.

The declaration also states that standard treatment with antibiotics would most likely be insufficient to observe improvement in Alzheimer's patients. However, note the instant claims encompass standard treatment..

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (703) 308-4616. The examiner can normally be reached on Monday to Friday from 9.00 a.m. to 6.00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist, can be reached on (703) 308-1701. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding

should be directed to the receptionist whose telephone number is (703) 308-1235.

elli peselev
ELLI PESELEV
PRIMARY EXAMINER
GROUP 1800